Amendment #2 to RFP-NIH-NIAID-DIR-04-01
"Operation of a Facility for the Testing of Malaria Vaccines in Adult Human Subjects"

Amendment to Solicitation No.:	NIH-NIAID-DIR-04-01
Amendment No.:	2
Issue Date:	December 9, 2003
Effective Date:	December 9, 2003
Proposal Due Date:	December 16, 2003,at 4:00 P.M. local time
Issued By:	Thomas P. Hastings Contracting Officer NIH/NIAID Contract Management Program 6700 B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Donald E. Collie, Contract Specialist dc128b@nih.gov
Name and Address of Offeror:	To All Potential Offerors

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this amendment. Failure to receive your acknowledgement of this amendment may result in the rejection of your offer. This amendment shall be acknowledged in the following manner:

- By acknowledging receipt of this amendment on each copy of the offer submitted.

RFP No. NIH-NIAID-DIR-04-01, paragraph 1 of the Statement of Work is replaced as follows:

Conduct approximately 6 staggered-start, dose escalating Phase 1 malaria vaccine trials per year in healthly volunteers aged 18 to 55. These vaccine studies will test the safety and immunogenicity of these vaccines. Vaccines will be recombinant protein vaccines formulated with one or more adjuvants. Recombinant antigens will be initially tested alone, and later as combinations. All trials will be done in an outpatient setting. Volunteers will not be challenged with malaria. Trials typically will use 39 volunteers in three dose groups (10 verum and three placebo per dose). Vaccinations will typically occur at time 0, 1 month and 6 months. Serological assessment will take place 14 days after each vaccination, and at 3, 6, 9 and 12 months. During vaccination and follow up visits, the facilities must be able to accommodate, where requested, limited involvement of MVDU staff and MVDU collaborators. The latter will include staff from institutions in endemic countries planning to undertake further Phase 1 and Phase 2 trials of the malaria vaccines to be tested under this contract. Such involvement would typically involve one to four appropriate qualified MVDU personnel being present during the vaccination and patient interviews to observe the procedure. Government (MVDU) scientists must also have ready access to examine volunteers and receive labile clinical specimens (e.g. whole blood samples) obtained from these volunteers as requested**.** The contractor would need to facilitate approval for these MVDU personnel to be present, ensure that there is sufficient room in the clinical suit used for vaccinations and patient interviews, that the extra staff members can be physically present, and to provide temporary desk space to enable MVDU personnel to prepare notes. The Project Officer shall provide biological suspensions that have been tested for purity and lack of contamination with adventitious agents and that will meet safety standards set by the NIH, the Center for Drugs and Biologics, FDA, and the Clinical Research Review Committees.